Status Report
of the
National Institutes of Health
in response to the

Focus Group
to Review
The Centers for AIDS Research (CFAR) Program

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National Institutes of Health

PREFACE

This document provides a status report developed in response to the report of the Focus Group to review the Centers for AIDS Research (CFAR) Program at the National Institutes of Health (NIH). The Focus Group report commissioned by the Director, Office of AIDS Research and the NIH institutes that co-fund the CFAR Program: the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), the National Institute on Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Heart, Lung, and Blood Institute (NHLBI), is the result of a comprehensive and objective review of the NIH CFAR program.

The NIH charge to the Focus Group was to address the role of the CFAR within the NIH AIDS research portfolio, the size of the program (e.g., number of centers and total funding), the criteria to be considered in determining funding levels, the milestones for its evaluation, and to determine what changes may further improve the CFAR program.

Under the chairmanship of Dr. Barney Graham, Vanderbilt University, the Focus Group developed a report with recommendations that was submitted to the Office of AIDS Research Advisory Council and the Councils of the relevant NIH Institutes and Centers. The NIH commends Dr. Graham and the members of the Focus Group for their efficient work and their cogent recommendations.

The Focus Group commended the CFAR program for its overall success and made recommendations for its future development that fall into four major categories: (1) the size and cost, (2) the application and evaluation process, (3) the administration of the program, and (4) the future goals. The overall recommendations and specific recommendations within each of these categories are addressed in this status document.

In general, the NIH concurs with all of the Focus Group's recommendations. NIH has developed a long-term budget plan for the program in response to the report, which will increase funding to approximately $30 million by FY 2003, create in response to the report a new tier of developmental awards beginning in FY 2001, and simplify and streamline the administrative and grants management procedures for the program. In addition, the NIH intends to address the recommendations focusing on the application and evaluation process in the development of a new program announcement for the CFARs. This will ensure that the spirit of the report recommendations will directly affect the future of the overall program.

Focus Group to Review
The Centers for AIDS Research (CFAR) Program
Recommendations

1. Recommendations for the Size and Cost of the CFAR Program

1.1 The size and overall proportion of the AIDS budget devoted to CFARs should be increased. It was felt that this should be done in a step-wise manner over the next three years and that it should be done with a minimal impact on the dollars devoted to R01 funding. Only 17 of 58 eligible sites have CFAR funding, and current CFARs are underfunded relative to other center programs such as the Cancer Centers, which are perceived to be highly successful.

NIH concurs with this recommendation and will plan to increase the budget for the CFAR program over the next four years as shown in Table 1. Funding for the program will continue to increase from approximately $9 million in FY 1997 to approximately $30 million by FY 2003, budget permitting. The number of sites will be maintained stable at about 18 with a funding cap of $1.5 million total costs per award site. It is anticipated that increased funding will be a result of funding new, eligible, CFARs at the $1.5 M cap, funding of Developmental CFARs (see recommendation 1.2), bridge funding as needed, and inflationary increases. Applications for CFAR funding will be accepted on an annual basis.

It was also emphasized that sustained growth of the program, particularly in terms of a percentage of the overall budget, should be contingent on improved outcome measures that can show added value of the CFAR program beyond funding of independent awards.

For NIH response, please refer to the response to recommendation 2.15

1.2 A multi-tiered system similar to that employed by the Cancer Center Program has many benefits including the distribution of smaller developmental awards for sites that need to increase a particular area of research activity in order to facilitate future collaborative interactions. This mechanism of distributing the funds for CFARs was preferred over an emphasis on multi-site CFARs. A two-tiered system of CFARs is recommended; the first tier being the current type of CFAR grant and the second tier being a developmental CFAR grant.

NIH concurs with this recommendation and will create a tier of Developmental CFARs starting FY 2001. One new site per year will be awarded to a total of three by FY 2003. These developmental centers will have a cap of $0.75 million total costs per site, for the duration of three years, and will be nonrenewable. Anticipating that some of these Developmental CFARs will compete to become CFARs, NIH is considering adding one additional CFAR to the 18 CFARs in FY 2003, assuming the NIH AIDS budget permits.

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1.3 The overall priority for applying additional funds should be to: 1) fund existing centers to the level approved by the study section; 2) increase the number of centers in part by adding a new category of developmental centers; and 3) gradually increase the cap applied to individual center grants.

NIH concurs with the overall recommendation for the prioritization of additional funding for the CFAR program. It is the intent of the NIH to fully fund new applications, based upon the study section recommendations and funding availability, and to allow the award of inflationary increases (currently 3% annually) over the cap of $1.5 million total costs per award.

In response to subpart 1, because of the increase in funding of the program over the next four years, the NIH will not be able to restore the administrative reduction in budget applied to all centers funded in FY 1998. The full budget implications of such a restoration became apparent when the long-term budget was developed. Because of the commitment to an annual recompetition, it will not be possible to restore funding for all 10 CFARs not funded for the full five years as this would effectively schedule all of these CFARs to terminate in the same year, reverting back to the five year competition schedule of the 1993 RFA.

In response to subpart 2, NIH will create a tier of Developmental CFARs starting in FY 2001.

In response to subpart 3, the caps will be reviewed for possible increases in the future.

1.4 The funding formula was felt to be appropriate and should remain as a sliding scale with a cap.

NIH concurs with this recommendation and the percentage of the research base will remain the same. The funding cap will remain at $1.5 million total costs for each new award.

1.5 Because there are 58 eligible sites under the current guidelines, it was not felt that the $6 million funding base criteria should be changed, and it was felt that first-time applicants should be eligible to apply for either tier level.

In response to this recommendation, NIH will retain eligibility at $6 million total costs for both the CFAR and the Developmental CFAR. The new program announcement for the CFAR program will emphasize that applicants can apply for either tier level.

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2. Recommendations for the Application and Evaluation Process

2.1 Because the CFARs are not directly involved in patient care or clinical protocols, as are Cancer Centers, the need for geographic distribution of centers was not felt to be acute, although regional distribution of center funding could be promoted by the award of smaller developmental applications.

2.2 Multi-site applications should not be denied, but should only be encouraged with exceptional levels of justification and evidence of uniquely organized communications systems. Exceptions to this would be linkages to minority institutions and to international sites, which foster the accomplishment of other important goals of the CFAR program.

2.3 The program announcement (PA) should state guidelines for the formation of multi-site groups and discourage artificially constructed collaborations.

In response to these recommendations, NIH will develop specific guidelines and review criteria for multi-institutional applications and will continue to monitor current multi-institutional CFARs for success with innovative communication systems and other strategies for meeting the challenges inherent with multi-institutional organizations.

2.4 The PA should emphasize the importance and value of recruiting minority faculty, training minority investigators, and collaborating with minority institutions in the CFAR application.

2.5 The PA should also promote interaction with international sites, training of international investigators, perhaps with links through the Fogarty program. This emphasis is critical for developing a larger group of investigators from populations with a particularly high endemic rate of HIV infection.

The NIH concurs with these recommendations and will emphasize the importance of encouraging minority investigators and CFAR collaborations with international sites in the new PA.

2.6 The PA should specify the criteria for defining the center type or tier of the applicant. This might include criteria such as the number of dollars in the research base, the number of investigators in the center, or the number of project areas in the application.

In response to this recommendation, the NIH will develop guidelines and review criteria specific to the Developmental CFAR. Both CFARs and Developmental CFARs will have the same funding base eligibility requirements of $6 million total costs. See recommendation 1.5.

2.7 Language should be developed in the PA that distinguishes a developmental award as distinct from the standard program/project-type application.

2.8 The application should balance the importance of science and the importance of management in the development of a successful center. The focus should be on how the center has facilitated, enhanced, or enriched scientific output from the site. The applicant should give examples of: 1) how leadership changes will be managed, 2) competence in setting criteria for investigator or core lab performance, 3) capacity for budget flexibility, 4) how CFAR leadership will add value to the institution's AIDS research program, and 5) how will pilot grants be awarded. The applications could be enhanced by organizing structure around programmatic themes.

2.9 Establishing well managed and efficient core functions should be emphasized above the overall number and breadth of Cores in a given application. The PA should emphasize the value of Cores that have a clear focus, and that directly contribute to translational research.

2.10 Both new and competing renewals should be evaluated by the same study section, and should have the same application format. There should be no restrictions placed on first-time applicants in terms of which tier they choose. While the emphasis on grants from new or renewing centers will be different, this is commonly dealt with by review panels, and the value of comparing applications between sites was felt to outweigh any value of an independent application process.

2.11 Although criteria should not be stipulated in the PA, it is critical for successful ongoing development of the CFAR program that institutional support be generated and sustained. Examples of institutional support should be listed in the PA such as: 1) the level of institutional funding, 2) space allocations, 3) co-funding, 4) endowments, and 5) designating the status of a center program in the institutional bylaws, to name a few.

2.12 Supplemental funding should not be done on a routine basis, and therefore no funds should be saved specifically for this purpose. However, if funds can be identified at the end of the fiscal year, all CFAR directors should be notified of the opportunity to submit a supplement request. The funds should be distributed based on a consensus opinion of the NIH Steering Committee of Program Officers administering the CFAR program.

2.13 The application process should be simplified by developing a series of tables, grids, and forms that could be part of each application, making the process more uniform and perhaps reduce the text needed to fully describe the organizational plan. The forms and tables should include data detailing the interaction between investigators at the site, and a listing of cores already at the site with a justification for any areas of potential overlap.

NIH appreciates the recommendation for the development of a series of tables, grids, and forms within the PA application and will explore this approach.

2.14 It was concluded that site visits and reverse site visits, while desirable in some instances, were not a necessary component of the evaluation process.

NIH concurs with the recommendation that site visits may not be a necessary component of the evaluation process, but may be conducted in the future at the discretion of the CFAR Steering Committee (comprised of program officers representing the NIH Institutes funding CFARs and an OAR representative) as these visits often provide valuable and useful information.

2.15 While much of the value of a center program is intangible, qualitative, and anecdotal, it was felt that more effort should be put into objectifying the measurement of added value. Examples of the impact of a center program might include lists of interdisciplinary manuscripts; new grant support for faculty previously funded by pilot projects; evidence of enhancement of existing programs; the use of core facilities; the number of protocols started within a single institution; other evidence of translational work, such as patent applications; and evidence of leveraging pilot studies into R01 funding or CFAR support into institutional support. This data should be used to evaluate the level or percentage of funds allocated to center programs in the future.

2.16 Application for CFAR funding should be available on an annual basis, and the number of competing renewals should be evened out so that they are approximately equal each year.

2.17 It was recommended that a uniform mechanism for reporting and evaluation criteria be established regardless of the affiliation of the principal project officer communicating with the site.

2.18 Awards should be for 5 years, but no less. Because of the nature of infrastructure building, and shorter period would be difficult to evaluate.

In response to this recommendation, it is the intent of the NIH to fund new applications for up to five years, based on funding availability, unless recommended otherwise by review committees.

NIH concurs with all of these 18 recommendations and will incorporate them into the CFAR PA.

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3. Recommendations for the Administration of the CFAR

3.1 It was stressed that the CFAR program should be a multi-Institute operation, and that cooperation among Institute administrations was just as important as the interactions among investigators at an individual site. A Steering Committee composed of program officers of the Institutes co-sponsoring CFARS and a representative of OAR was recommended, but each CFAR unit should only report to one designated project officer.

NIH has implemented this recommendation. The NIH CFAR Steering Committee is actively working to implement the report's recommendations and develop a multidisciplinary vision for the program. The committee includes program officers of the Institutes co-sponsoring the program and an OAR representative. In the future all CFARs will be administered by NIAID and will report to one program officer at NIAID. The Steering Committee members will provide their scientific expertise and program management experience to decisions concerning CFAR management issues.

3.2 The mechanism of budgeting and fund allocation for each CFAR site should be uniform.

NIH concurs with this recommendation. As this is an internal administrative issue, NIH has already taken the appropriate steps in order to simplify and streamline the funding and grants management aspects of the CFAR program. In the future CFAR grants will be administered by NIAID with a single NIAID program officer with scientific input from the Steering Committee.

3.3 If a competing renewal application is not funded, the site should receive bridge funding at a level of 50 % of the prior budget for one year to help maintain the infrastructure investment made at the site until a revised application can be evaluated.

NIH concurs with this recommendation. Bridge funding will be provided at 50 per cent for one year to unsuccessful renewals. Table 1 reflects the allocation of specific funds for this purpose.

4. Recommendations for the CFAR Goals

The CFAR mission statement is clear and appropriate. However, it was recommended that a greater emphasis be placed on some approaches used to accomplish that mission. It was agreed that the primary focus should be to stimulate interactions between established research programs. However, it was felt that more emphasis should be placed on promoting the development of future investigators, either through support and mentoring of junior faculty or attraction of established investigators into the field of HIV-related research. A special emphasis should be placed on training investigators from minority groups and worldwide areas with high endemic rates of HIV infection. It was suggested that the PA list mechanisms for achieving these goals. The list could be generated from strategies already established in the existing CFAR programs and could include other ideas, such as awards or other forms of recognition for outstanding junior faculty members, or mini-sabbaticals for investigators to spend 1-3 weeks at another site to learn a new technique.

In response to this recommendation, the NIH will incorporate these concepts into the issuance of the new PA.